

# **Defendants'**

## **Exhibit 4**

UNITED STATES DISTRICT COURT FOR  
THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

TRANTAFYLLOS TAFAS,

Plaintiff,

v.

JON W. DUDAS, *et al.*,

Defendants.

CIVIL ACTION: 1:07-CV-846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM  
CORPORATION, *et al.*,

Plaintiffs,

v.

JON W. DUDAS, *et al.*,

Defendants.

CIVIL ACTION: 1:07-CV-1008 (JCC/TRJ)

DECLARATION OF JENNIFER M. MCDOWELL

I, Jennifer M. McDowell, hereby declare:

1. I am employed by the United States Patent and Trademark Office ("USPTO") as an attorney in the USPTO's Office of General Counsel, Office of General Law, and I have been so employed since before January 3, 2006.
2. As an attorney in the Office of General Law, I was responsible for the administrative clearance of the rulemaking that culminated in the "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct

Claims, and Examination of Claims in Patent Applications.” 72 Fed. Reg. 46716 (Aug. 21, 2007) (“Final Rules”).

3. In connection with these duties, I have knowledge of the record-keeping practices of the USPTO relating to rulemakings generally and the referenced rulemaking specifically.
4. On October 5, 2007, I filed a Certification with this Court that the documents listed in the Index of Administrative Record and filed with the Court on the same date are, to the best of my knowledge, a true, correct and complete copy of the administrative record in this matter.
5. The USPTO included in its administrative record all non-privileged materials and documents that the agency decision-maker indirectly or directly considered in connection with the Final Rules. Put differently, the administrative record filed with this Court includes all non-privileged materials or documents that might have influenced the agency’s decision to promulgate the Final Rules.
6. I explained in the Certification that “[p]rivileged documents reflecting internal agency deliberations, attorney-client communications, and attorney work product have been excluded from the administrative record. See e.g., Nat’l Courier Ass’n v. Bd. Of Governors of Fed. Reserve Sys., 516 F.2d 1229, 1241-43 (D.C. Cir. 1975); Amfac Resorts, L.L.C. v. U.S. Dep’t of the Interior, 143 F. Supp. 2d 7, 13 (D.D.C. 2001). Where only a portion of a document is privileged, the privileged information has been redacted. Any unpublished patent applications or patent application identifiers that were utilized or considered during the rule making process have been excluded or

redacted pursuant to 35 U.S.C. § 122. Additionally, information protected by the Privacy Act of 1974, as amended, 5 U.S.C. § 552, has been redacted from the record.”

7. If the USPTO were now required to produce a privilege log of documents withheld from the administrative record because they are deliberative in nature, between twenty and thirty employees would have to devote innumerable hours to collecting and reviewing more than two years’ worth of their internal communications related to the Final Rules.
8. These communications would include, among other categories of documents: e-mails, memoranda, drafts of the Final Rules and Federal Register notices, contributions to internal discussion boards, issue papers, meeting notes, and more.
9. I estimate that there are at a minimum, several hundred privileged documents, and very possibly thousands of such documents.
10. I am familiar with the document at A04546-A04553, which I understand that GlaxoSmithKline has designated as “Exhibit B” to its Memorandum in Support of Its Motion for Entry of an Order Requiring Defendants to Submit a Privilege Log.
11. “Exhibit B” contains “issue papers” on various topics related to the Final Rules that were compiled and given to Under-Secretary of Commerce Jon Dudas. The redacted portions of the document provided subjective advice and recommendations to the Under-Secretary. The unredacted portions contain objective data.
12. I am also familiar with the document at A08414-A08419, which I understand that GlaxoSmithKline has designated as “Exhibit C” to its Memorandum in Support of Its Motion for Entry of an Order Requiring Defendants to Submit a Privilege Log.

13. "Exhibit C" contains an e-mail and document prepared by Mr. Rick Nydegger, which agency officials forwarded to each other internally. The redacted portion of the exhibit merely contains internal "forwarding" e-mails that are transmittal in nature and therefore do not constitute materials that might have influenced the agency's decision to promulgate the Final Rules.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: November 20, 2007

  
JENNIFER M. MCDOWELL